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UNITED STATES DEPARTMENT OF COMMERCE
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#14

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,670,455, which issued June 2, 1987, was filed on May 10, 1996, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, DOMITOR®, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within sixty days after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. However, it is noted that an application for patent term extension of U.S. Patent No. 4,544,664 has also been filed. Should both patents be eligible for extension of the patent term, election of a single patent will be required.

Hiram A. Bernstein
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cc: Charles E. Van Horn
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